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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,341	04/14/2004	Gary W. Guent	P-10073.00	5392
27581	7590	03/29/2007	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			TYSON, MELANIE RUANO	
			ART UNIT	PAPER NUMBER
			3731	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/29/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,341	GUENST, GARY W.	
	Examiner	Art Unit	
	Melanie Tyson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 32-42 is/are pending in the application.
- 4a) Of the above claim(s) 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16-20 and 32-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/30/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election **without traverse** of Invention I, Species II, in the reply filed on 31 January 2007 is acknowledged. Applicant has cancelled claims 21-31 without prejudice. Claim 15 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, 4, 9, 14, 32, 33, 35, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Stanish (Patent No. 6,585,762 B1). Stanish discloses a method of implanting grafts (see entire document) comprising the steps of making an incision in the blood vessel wall, inserting a tubular member (465) into a conduit (480; for example, see Figure 11), advancing the tubular member (465) through the incision, and suturing the conduit (480) to the blood vessel while providing an oxygenated liquid flow (blood) through the tubular member (for example, see column 9, lines 23-29, and Figure 11).

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4. Claims 1, 7, 32, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Butters et al. (Patent No. 6,019,788). Butters et al. disclose a method of implanting grafts (see entire document) comprising the steps of making an incision (135; for example, see Figure 3) in the blood vessel wall (31), inserting a tubular member (16/22) into a conduit (28), advancing the tubular member (16/22) through the incision (135), fixedly joining the conduit (28) to the blood vessel while providing an oxygenated liquid flow through the tubular member (for example, see column 7, lines 16-19 and column 8, lines 15-19), and expanding the tubular member distal region (22) outward (for example, see Figures 11A-11D).

5. Claims 1, 10, 14, 17, 32, and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Finch et al. (Patent No. 6,042,569). Finch et al. disclose a method of implanting grafts (see entire document) comprising the steps of making an incision in the blood vessel wall, inserting a tubular member (206/230; for example, see Figures 9 and 10) into a conduit (202), advancing the tubular member (206/230) through the incision, and fixedly joining the conduit (202) to the blood vessel while providing an oxygenated liquid flow (blood, drugs, or other media; for example, see column 2, lines 57-60) through a port (100) into the tubular member (for example, see column 9, lines 38-42). Since liquid flow is regulated by a pressure responsive valve, it is inherent the fluid flows through the tubular member at a higher pressure than the patient's blood pressure.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 3 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butters et al. Butters et al. disclose inserting a tubular member into a conduit (see rejection above). Applicant has disclosed that the inserting may be performed either before or after advancing (see claim 2), therefore, inserting after advancing is simply a reversal of steps which involves only routine skill in the art.

9. Claims 5, 6, 11, 12, 13, 18, 19, 20, 36, 37, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finch et al. in view of Galdonik et al. (Publication No. 2002/0091398). In addition to the steps described above, Finch et al. further disclose the device may be implanted within a variety of arteries and veins (for example, see column 4, lines 16-20) and may be used to join arteries and veins, which are attached to each other by an end-to-end anastomosis (column 4, lines 48-50), and

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thus are supplied with blood that has gone through the femoral artery or aorta at one point or another. Finch et al. do not disclose specifically that the conduit is a saphenous vein. Galdonik et al. disclose medical grafting methods (see entire document). Galdonik et al teach inserting a tubular member (300; for example, see Figure 21) into a conduit (typically a saphenous vein graft 14 but well known may be an internal mammary artery; for example, see paragraphs 3 and 16) and joining it with a blood vessel (coronary artery 20) and further retracting the tubular member (300). Galdonik et al. further teach inserting a stiffening member (wire 406) inside the tubular member (300). It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the device of Finch et al. with the conduits taught by Galdonik et al. in order to be able to form an anastomosis with reduced vessel stenosis, thrombosis, and perforation (Finch et al., column 2, lines 3-10).

10. Claims 8 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butters et al. in view of Blum (Patent No. 4,230,119). Butters et al. disclose a device as described above, however, fail to disclose a flow restrictor and a weakened wall region. Blum discloses a device utilized during an anastomosis (see entire document). Blum teaches a tubular member having a flow restrictor (21) and a weakened wall region (19), wherein expanding includes forcing fluid under pressure through the tubular member to expand the weakened distal region. It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the tubular member as taught by Blum in order to eliminate the step of sizing vessels by providing a device that can

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accommodate different sized vessels, thus facilitating the procedure (for example, see column 1, lines 61-68).

11. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Finch et al. Finch et al. disclose a device as described above, however, fail to disclose pressure is provided by a bulb. It is well known in the art to use bulbs to provide pressure, therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize a bulb to provide fluid pressure through the tubular member. For example, Blum (Patent No. 4,230,119) discloses a bulb (13) for providing fluid pressure to a tubular member during an anastomosis procedure.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Tyson whose telephone number is (571) 272-9062. The examiner can normally be reached on Monday through Friday 9:00 a.m. - 5:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie Tyson
March 27, 2007

MT

[Signature]
ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

2/28/07